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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,248	10/16/2001	Pamela M. Holland	2499-1-001N	4112

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,248	HOLLAND ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-45* is/are pending in the application.

4a) Of the above claim(s) *8-19,21-28 and 30-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,29 and 35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/07/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence alignments.*

The Response to Election/Restriction and Amendment filed on October 27, 2003 is acknowledged. The Preliminary Amendment filed on Nov. 13 2003 is acknowledged. Claims 1-7 are canceled; new claims 35-45 are entered. Claims 8-19, 21-28 and 30-34 are withdrawn from the examiner's consideration as directed to the non-elected invention. Claims 20, 29 and 35-45 are the subject of this Office Action.

DETAILED ACTION

1. Election/Restriction

Applicant's election, with traverse, of Group I directed to isolated GID polypeptide of original claims 1-7, 20 and 29, is acknowledged. Claims 1-7 have been cancelled. The elected invention reads on claims 20, 29, and 35-45.

The traversal is on the ground(s) that claims of Group IV and V, as directed to the method of use of the product of Group I, should be included in examination and restriction at least between Group I, IV and V should be withdrawn.

Applicant's traverse has been fully considered. In case the product of Group I is found allowable pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims of Group IV and V directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, will be rejoined.

2. Objections

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Claims 20 is objected as depending on claims 19 drawn to non-elected subject matter. Please amend the claim to the independent form.

Claim 40 misses the word "wherein' in the first line, immediately after the word "activity".

3. Rejections

3.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 40 is rejected because the claim recites the term "hybridizing to (a) under moderately stringent conditions", which renders the claim indefinite. The examiner acknowledges exemplifying moderately hybridization conditions on page 19, line 33 of the application. However, conditions are merely exemplified and there is nothing to suggest that other hybridization conditions are not intended to be included. In the art what conditions are considered "moderately stringent" varies widely depending on the experiment and person making the determination. Therefore, it is unclear how homologous to a sequence comprising nucleotides 646 through 1183 of SEQ ID NO: 1

a sequence must be to be within the scope of the claim. Specifying the hybridization conditions in the claim will overcome this rejection.

Claim 40 is also confusing in recitation of nucleotides 646-1183 of SEQ ID NO: 1. It is assumed that Applicants refer to nucleotides that encode the catalytically active fragment of SEQ ID NO: 2 (amino acids 216-395). This fragment is encoded by nucleotides 646-1185.

Claim 43 is indefinite because it recites amino acids residues 581 through 584 without identifying the amino acid sequence of the claimed polypeptide. Also claim 40, from which claim 43 depends, does not disclose any amino acid sequence having amino acids residues 581-584.

2.2. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Lack of written description

Claim 29, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 is directed to a solid support comprising fragment of the GID polypeptide capable of binding sGNK. The disclosure is failing to identify any fragment of GID that binds to GNK and its substrate. The specification identifies only the full SEQ ID NO: 2 and the fragment of GID that has decarboxylase activity, amino acids 216-395 of SEQ ID NO: 2 (page 15).

Because the Applicants did not described any fragment of GID that binds to GNK and its substrate, one skilled in the relevant art is not convinced that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 42 is directed to a polypeptide having decarboxylase activity and encoded by a nucleic selected from the group comprising:

(a) nucleotides 646-1183 of SEQ ID NO: 1,

(b) a nucleic acid capable of hybridizing to (a) under moderately stringent conditions, and

(c) a nucleic acid that due to degeneracy of the genetic code, encodes a polypeptide encoded by (a) or (b),

wherein said polypeptide is not cleavable by caspase-3.

Claim 42 is lacking written description of structure. Applicants disclose only one representative species of the claimed subgenera, i.e. the DNA molecule consisting of nucleotides 646-1183 of SEQ ID NO: 1. This molecule encodes the fragment of SEQ ID NO:2 that has decarboxylase activity, but, because the fragment is lacking amino acids

581-584 it is not cleavable by caspase-3. Teaching only one representative species of the genus does not provide a sufficient identifying structural characteristics of claimed subgenera.

Applicants also disclose SEQ ID NO: 1, which comprises nucleotides 646-1183 of SEQ ID NO: 1, this sequence, does not encode a sequence that is not cleaved by caspase-3. SEQ ID NO:1 encodes SEQ ID NO: 2 that is cleavable by caspase 3 because it comprises amino acids 581-584, the caspase-3 cleavage site. To make SEQ ID NO: 2 not cleavable by caspase-3, one has to change amino acids 581-584 in a way not taught by Applicants. Applicants disclose SEQ ID NO: 2 and demonstrate that the sequence is cleaved by caspase-3, but Applicants only assume that changing any of amino acid residues 581-584, i.e., DNVD, result in the loss of cleavage site for caspase 3. Absent of the experimental evidence, one skilled in the art is not convinced that Applicants have the claimed invention, because caspase-3 cleaves other sequences than DNVD.

For example, caspase-3 cleaves the sequence DEMD of Mst1 used as a control substrate by Applicants on page 54 of the specification. Caspase-3 cleaves also the sequence DSYD, see the article by Vito et al. 1997, enclosed. The last two tetrapeptides are obtained by change of two internal amino acids of the DNVD sequence, thus, they are species of a genus of "at least one amino acid change in any of the amino acid residues 581 through 584", however they are still cleavable by caspase –3.

2.2. 35 USC section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 20, 29, 35-42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by the WO document WO200153312-A1 issued on 26 July 2001 with priority to the US application No 09/620,312 filed on July 19, 2000; enclosed in the Information Disclosure Statement.

Claims 29, 35-42 and 44 are directed to an isolated polypeptide comprising an amino acid sequence that is in at least 80% identical to amino acids residues 216-395 of SEQ ID NO: 2 and having a decarboxylase activity.

WO document discloses as SEQ ID NO: 2240 an amino acid sequence that is identical to amino acid sequence of SEQ ID NO: 2 of the instant application. Thus, SEQ ID: 2240 comprises in positions 216-395 amino acid 216-395 of SEQ INO: 2 of the instant application; see the attached alignment.

Claim 20 is rejected because the document also discloses the DNA sequence of SEQ ID NO: 454, a 3964 bp long sequence that comprises in positions 174-2540 the whole nucleotide sequence of SEQ ID NO: 1of the instant application; see the enclosed sequence alignment. Thus, SEQ ID NO: 454 of the document encodes a polypeptide that comprises SEQ ID NO: 2. The WO document teaches on pages 18-20 the use of

SEQ ID NO: 454 for the expression and recombinant production of the encoded polypeptide. Therefore, WO document anticipates also claim 20, depending on claim 8, as claim 20 is directed to a recombinantly produced polypeptide encoded by an isolated nucleic acid encoding a ID polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or its biologically active fragment.

2.3. 35 USC section 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO document WO200153312-A1 issued on 26 July 2001 with priority to the US application No 09/620, 312 filed on July 19, 2000, in view of common knowledge in the field of biotechnology.

Claim 45, is directed to a fusion polypeptide comprising a polypeptide comprising an amino acid sequence that is at least 80% identical to the amino acid residues 216-395 of SEQ ID NO: 2.

WO document discloses a DNA sequence of SEQ ID NO: 454, 3964 bp long, which comprises in positions 174-2540 the whole nucleotide sequence of SEQ ID NO: 1 of the instant application; see the enclosed sequence alignment. Thus, SEQ ID NO: 454 of the prior art encodes a polypeptide that comprises SEQ ID NO: 2 of the instant application, which is a sequence that comprises an amino acid sequence that is at least 80% identical to the amino acid residues 216-395 of SEQ ID NO: 2 of the instant application.

The WO document does not teach the production of a fusion protein as claimed by claim 45 of the instant application, however WO document teaches how to recombinantly produce amino acid sequence identical to SEQ ID NO: 2 of the instant application; see pages 18-20. It would have been obvious to one having ordinary skill in the art at the time of invention to modify teachings of the WO documents so that the expression vector also encoded a fusion protein polypeptide comprising amino acid sequence that is at least 80% identical to the amino acid residues 216-395 of SEQ ID NO: 2 because the fusion peptides are routinely used in biotechnology for an efficient isolation of recombinantly produced proteins of interest.

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

3. Conclusion

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Patent Examiner
Art Unit 1652

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600